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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,162	03/07/2002	Yoshihiro Sowa	14875-008001/C1-101PCT-US	4957

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EXAMINER	
GODDARD, LAURA B	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/937,162	SOWA ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-10,14-17,21-24 and 27-29* is/are pending in the application.

4a) Of the above claim(s) *21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10,14-17 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/9/03, 3/7/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed January 11, 2007 in response to the Office Action of October 25, 2006, is acknowledged and has been entered. Previously pending claim 6 has been amended. Claims 11-13, 18-20, and 25-26 are canceled. Claims 21-24 are withdrawn. Claims 6-10, 14-17, and 27-29 are currently being examined.

Foreign Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Priority has been claimed to Japanese application 11/77350 in the oath/declaration submitted 10/30/2002, however priority has not been stated in the first line of the specification or in an application data sheet. MPEP 201.11 states: "The later-filed application must contain a reference to the prior-filed application in the first sentence(s) of the specification or in an application data sheet, for a benefit claim under 35 U.S.C. 120, 121, or 365(c), and also for a benefit claim under 35 U.S.C. 119(e)".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "wherein the fusion protein lacks **at least part of a zinc finger region** selected from the group consisting of amino acids 495-517, 525-547, and 555-575 of human Sp3". It is unclear if only a part of the recited zinc finger regions are lacking or if the entire recited amino acid regions are lacking. For example, is only a part of the zinc finger 495-517 region lacking or is the entire 495-517 region lacking?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 6-10, 14-17, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying an agent that activates TSA-responsive Sp3-mediated transcription, comprising: providing a cell having (a) a first vector comprising a first regulatory sequence operably linked to a nucleic acid sequence encoding a fusion protein, wherein the fusion protein comprises (i) a fragment of human Sp3 having transcriptional activity comprising at least one glutamine-rich region of TSA-responsive domain of Sp3 **and lacking at least amino acid residues 495-517, 525-547, 555-575 of the Zinc finger region,** does not reasonably provide enablement for a said method with a fusion protein comprising a fragment of human Sp3 having transcriptional activity comprising at least one

glutamine-rich region of TSA-responsive domain of Sp3 **and lacking at least part of a Zinc finger region of Sp3**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a method of identifying an agent that activates TSA-responsive Sp3-mediated transcription, comprising: providing a cell having (a) a first vector comprising a first regulatory sequence operably linked to a nucleic acid sequence encoding a fusion protein, wherein the fusion protein comprises (i) a fragment of human Sp3 having transcriptional activity comprising at least one glutamine-rich region of TSA-responsive domain of Sp3 and lacking at least part of a Zinc finger region of Sp3, which broadly encompasses lacking any sized portion anywhere in the Zinc finger region of Sp3.

The specification discloses that the region having transcriptional activation capacity of the Sp3 protein is not limited as long as it contains a region capable of transcriptional activation in response to a TSA stimulus and that such a region desirably comprises at least a part of the transcription activation domain and lacks at least part of the DNA binding domain (zinc finger region). The specification discloses that the claimed screening method is possible even in the presence of the DNA binding region derived from Sp3 but the presence of this DNA binding domain or zinc finger is not desirable because a fusion protein comprising this region can bind to various endogenous Sp1 binding sequences. Further, the specification discloses that in the case of human Sp3 protein, a desirable region comprises at least one of the two

glutamine-rich regions (amino acids 495-517, 525-547, and 555-575), and lacks at least part of the zinc finger region (amino acids 495-517, 525-547, and 555-575) (p. 7, lines 5-17). The specification does not disclose any other Sp3 fragments lacking *any part* of the Zinc finger region that would function in the claimed method as broadly encompassed in the claims.

One cannot extrapolate the disclosure of the specification to the scope of the claims because the specification does not provide guidance or support for identifying an agent that activates TSA-mediated Sp3-mediated transcription comprising using a fusion protein comprising a fragment of Sp3 lacking *any part* of a Zinc finger region as broadly claimed. The specification discloses Sp3 fragments functioning as claimed that lack the entire Zinc finger motif (see Figure 3; Example 3) or amino acids 495-517, 525-547, and 555-575 of human Sp3 (p. 7, lines 9-16). In view of the disclosure of the specification that the presence of the Zinc binding domain is not desirable in the fusion protein because this region can bind to various endogenous Sp1 binding sequences, it would be expected that the inclusion of the specifically cited residues in the fusion protein or even parts of them would lead to identification of numerous species that are not associated with Sp3 transcription and thus it could not be predicted which or how many of the identified species would in fact be affecting Sp3 transcription and which would function as claimed.

Further, Majello et al (J Biological Chemistry, 1997, 272:4021-4026, IDS) teach that Sp3 is a bifunctional transcriptional regulator containing independent modular repressor and activator domains. The activator potential of Sp3 is distributed over an

extensive glutamine-rich N-terminal region and the negative regulatory function has been mapped 5' of the zinc finger region. The reference teaches that the Sp3-repression ability is strikingly dependent upon the context of the Sp3 DNA-binding sites present in the reported promoters. Sp3 functions as a repressor when it is bound to the promoter through multiple DNA-binding sites. Sp3 is an activator when it is targeted to the promoter via a single binding site (p. 4021, col. 2). The reference teaches that different allosteric changes may occur depending upon the context of DNA-binding sites, allowing mutual exclusive interactions between diverse Sp3 domains and putative cofactors leading to a different transcription response (p. 4025, col. 2). Finally, the reference teaches that Sp3 repression ability is also dependent upon the cellular context (p. 4025, col. 2).

Considering the disclosure of the specification and teachings of Majello et al, it would be expected that an Sp3 fragment which includes a zinc finger region or a functional part of a zinc finger region would bind Sp1 binding sequences instead of Sp3, and that Sp3 can potentially function as a transcriptional repressor instead of an activator depending upon the DNA binding domains present in the promoter region, hence, the claimed method would not function without transcription activated by Sp3. A method of identifying an agent that activates TSA-responsive Sp3-mediated transcription comprising a vector encoding a fusion protein that comprises an Sp3 fragment containing any Zinc finger region, more than one region, or part of a region would not predictably function as claimed.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be reasonably predicted that the claimed method of identifying an agent that activates TSA-responsive Sp3-mediated transcription will predictably function as disclosed. Therefore, in view of the lack of predictability of the prior art, lack of guidance in the specification, the breadth of the claims and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

5. All other rejections and objections recited in the Office Action mailed October 25, 2006 are hereby withdrawn.

6. **Conclusion:** No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

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